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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/803,773	03/12/2001	Judah Z. Weinberger	56330-A/JPW/PJP	8786

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04/19/2004

Cooper & Dunham LLP
1185 Avenue of the Americas
New York, NY 10036

EXAMINER

MARMOR II, CHARLES ALAN

ART UNIT	PAPER NUMBER
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3736

16

DATE MAILED: 04/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/803,773

Applicant(s)

WEINBERGER, JUDAH Z

Examiner

Charles A. Marmor, II

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-11 and 22-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 25-29 is/are allowed.
- 6) ☒ Claim(s) 1-4,6-11 and 22-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed December 22, 2003. The Examiner acknowledges the amendments to claims 1, 8 and 22. Claims 1-4, 6-11 and 22-29 are pending.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 3, 7, 8, 10 and 22 rejected under 35 U.S.C. 102(e) as being anticipated by Klein ('284). Klein teaches an apparatus for radiation treatment of an internal body lumen. The apparatus includes a balloon catheter **34** having an inflatable balloon **32** and a tube segment (radiation-emitting sleeve catheter **10**) that is adapted to be longitudinally slid over, carried by and cover the balloon. The tube segment **10** includes a radioactive material **30,302** that is mixed with a non-radioactive material **38** (col. 24, lines 65-67). The tube segment **10** can be an expandable and collapsible material, such that the tube segment is expandable in a range of sizes and the shape of the tube segment is determined by the shape of the balloon as the balloon inflates to expand the segment and deflates to collapse the segment. Embodiments of the tube segment **10** are formed of an elastomeric material that covers the balloon substantially entirely

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during inflation (col. 12, lines 35-39 and Figs. 5-6). The outer surface of the tube segment **10** is exposed to come into direct contact with the luminal structure. In operation, the balloon catheter **34** is inserted into the body lumen; the radioactive tube segment **10** is longitudinally slid over the balloon catheter **34** such that the tube segment including the radioactive material **30,302** is disposed over the balloon **32**; the balloon **32** is inflated with fluid to expand the tube segment **10** and administer a radiation dose to the luminal structure; the balloon **32** is deflated and the tube segment **10** collapsed; and the balloon catheter **34** and tube segment **10** are removed from the luminal structure.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 2 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein ('284) in view of Hess ('168). Klein teaches all of the limitations of the claims except that the radioactive material is in the form of a coating on the tube segment. It is well known in the art that a non-radioactive material can be provided with radioactive characteristics by coating the non-radioactive material with a radioactive material. Hess teaches a stent **74** which is coated with a radioactive material in order to assist in preventing restenosis of an artery. It would have been an obvious engineering design choice to one skilled in the art at the time the invention was made to make a radioactive tubular segment similar that of Klein by coating a tubular segment

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with a radioactive material in view of the teachings of Hess in order to produce a tube that is radioactive at its distal end. .

6. Claims 4 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein ('284) in view of Lewis et al. ('552). Klein teaches all of the limitations of the claims except that the tube segment includes a non-radioactive material into which is absorbed radioactive material. Lewis et al. teach that it is known in the art to make intra-luminal radiation devices of a non-radioactive material into which is absorbed radioactive material. It would have been an obvious engineering design choice to one skilled in the art at the time the invention was made to make a radioactive tubular segment similar that of Klein by absorbing radioactive material into a non-radioactive material in view of the teachings of Lewis et al. in order to produce a tube that is radioactive at its distal end.

7. Claims 6, 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein ('284) in view of Fischell et al. ('282). Klein teaches all of the limitations of the claims except that the tube segment is adhesively attached to the balloon and that the balloon is inflated with a gas. Fischell et al. teach a catheter having an expandable radioactive source. The catheter includes a balloon **14** with an expandable, elastic radioactive tube segment **16** adhesively attached to the balloon **14** by an outer balloon **15** which is heat sealed (shrunk) to the inner balloon (col. 5, lines 2-6). The balloon **14** is inflated with a carbon dioxide gas to bring the tube segment into proximity to a luminal structure (col. 6, lines 51-53). It would have been obvious to one having ordinary skill in the art that since the radioactive source **16** is expandable and

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elastic, the dosage per surface area of the source would inherently be different in an inflated state than that of the unexpanded state. It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to adhesively attach the tube segment to the balloon of a radiation treatment device similar to that of Klein in view of the teachings of Fischell et al. in order to ensure proper positioning of the expandable radioactive tube segment with respect to the balloon. It further would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to use a carbon dioxide gas as an inflation medium in view of the teachings of Fischell et al. in order to inflate the balloon catheter of a device similar to that of Klein as an obvious engineering design choice, merely substituting one known inflation medium for another that is capable of performing the same function.

Allowable Subject Matter

8. Claims 25-29 are allowed over the prior art of record.
9. The following is an examiner's statement of reasons for allowance:

No prior art of record teach or fairly suggest a tube segment for treating a disease process, as claimed by Applicant in claims 25-29, where the tube segment has varying concentrations of radioactive material for producing a radioactive dose that varies along at least one dimension of the tube segment while having a substantially equal wall thickness along its longitudinal length.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

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fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Response to Arguments

10. Applicant's arguments with respect to claims 1-4, 6-11 and 22-24 have been considered but are moot in view of the new ground(s) of rejection. In regard to independent claims 1, 8 and 22, Applicant contends that although the stent taught by Hess ('466) may be removable, it does not necessarily teach that the stent is collapsible, as claimed, as there are other acceptable means of removing the stent. Applicant further contends that Hess does not teach that the tube segment is not expanded and collapsed as the balloon is expanded and deflated. These arguments have been fully considered but are moot in view of the new grounds of rejection citing Klein ('284) set forth hereinabove.

The new grounds of rejection citing Klein ('284) were formerly set forth in the Office Action mailed May 14, 2003. In response to that Office Action, Applicant argued that Klein teaches a tube segment having a plurality of longitudinal slits that expose portions of the balloon when the balloon expands the tube, and consequently fails to teach or suggest that the tube segment entirely encircles and covers the balloon. This argument is not persuasive. While one embodiment of the tube segment of Klein includes a plurality of longitudinal slits (Figs 3-4A) as pointed out by Applicant, this is only one embodiment of the tube segment taught by Klein. Klein also teaches tube segments formed of an elastomeric sleeve (Figs. 5, 6, 11 and 12) or a sleeve of polymeric material having a plurality of folds (Figs. 7-10), where the tube segment will cover the balloon substantially entirely during inflation and deflation. These embodiments of the

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Klein apparatus read on all of the limitations of independent claims 1, 8 and 22 of the instant application.

Applicant further argued in response to the rejections of the Office Action mailed May 14, 2003 that the outer surface of the tube segment of present invention is exposed and that this feature is not taught or suggested by Klein. This argument also is not persuasive. Claims 1, 8 and 22 require that the tube segment includes a radioactive material and that the outer surface of the tube segment is exposed to come into direct contact with the luminal structure. The tube segment 10 of Klein includes a radioactive material 30,302 and an outer surface of the tube segment 10 is exposed to come into direct contact with the luminal structure. Therefore, Klein meets all of the limitations of claims 1, 8 and 22 of the instant application as claimed.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

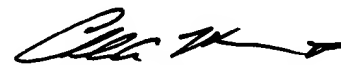
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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (703) 305-3521. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Beth Jones can be reached on (703) 308-3400. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles A. Marmor, II
Primary Examiner
Art Unit 3736

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April 5, 2004